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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,483	10/13/2000	Andreas Braun	24736-2033	7859
20985	7590	11/04/2004	EXAMINER	
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			CLOW, LORI A	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/687,483	Applicant(s) KOSTER ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,9-15,31-34,43,44,47-50,54 and 98-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,9-15,31-34,43,44,47-50,54 and 98-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/6/04; 4/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' response, filed 29 August 2004 has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 4, 5, 9-15, 31-34, 43, 44, 47-50, 54, and 98-125 are currently pending.

Information Disclosure Statement

The Information Disclosure Statements filed 6 February 2004 and 20 April 2004 have been considered. Signed copies of PTO Forms 1449 are included with this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 5, 9-15, 31, 43, 44, 47-50, 109-125 remain rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al. (WO 98/35609) for the reasons set forth in the previous Office Action.

Applicant argues that “the specification discloses a strategy to identify polymorphisms using the healthy subject database that does not require comparison to a diseased population. As discussed above, the instant application provides methods to identify polymorphisms and other

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markers that may be related to a pre-determined parameter, such as age, sex, or ethnicity, without prior knowledge of their existence, by stratifying information in healthy subject databases (information from individuals selected only on the basis of being healthy) according to pre-determined parameters. Any marker that exhibits a statistically significant frequency change as a function of the parameter is a candidate for further investigation”.

This argument is not persuasive because, while it may be true that the specification discloses a strategy to identify polymorphisms using the healthy subject database that does not require comparison to a diseased population, the claims do not read as such. The claims recite, “a method of producing a database **comprising**: selecting only healthy members of a population of organisms not manifesting any disease state”. The claims do not exclude the fact that a database could contain both healthy population data, as well as disease population data in subsets, as is disclosed in Campbell et al. Campbell et al. disclose, as was previously stated, a computer-based system for predicting the future health of individuals comprising biomarker values from individual members of a test population. The population consists of two subpopulations, those having acquired a specified biological condition and those not having acquired the specified biological condition (abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32-34, 99, 100, and 102 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaughhey et al.), in view of Campbell (WO 98/35609), in further view of US 5,498,545 (Vestal), for the reasons set forth in the previous Office Action.

Applicant argues that neither Bullaughhey et al. nor Vestal teach or suggest a healthy subject database. However, Campbell et al. is relied upon to teach this limitation. No other arguments are presented in reference to Campbell et al.

Claims 54 and 101 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaughhey et al.), in view of Campbell (WO 98/35609).

Applicant argues that Bullaughhey et al. do not teach or suggest a healthy subject database. However, Campbell et al. is relied upon to teach this limitation. No other arguments are presented in reference to Campbell et al.

Claim 98 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell (WO 98/35609), in view of US 5,498,545 (Vestal), for the reasons set forth in the previous Office Action.

Applicant argues that Vestal does not teach or suggest a healthy subject database. However, Campbell et al. is relied upon to teach this limitation. No other arguments are presented in reference to Campbell et al.

Claims 103-108 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaughhey et al.), in view of Campbell (WO 98/35609), in view of US 5,498,545

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(Vestal), in further view of US 6,602,662 (Koster et al.), for the reasons set forth in the previous Office Action.

Applicant presents the same argument as above in reference to Koster et al. Again, Campbell et al. is relied upon to teach this limitation. No other arguments are presented in reference to Campbell et al.

Conclusion

Rejections under 35 USC 101 have been withdrawn in view of Applicant's response.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

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in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center Number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

November 2, 2004
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
11/1/04